BRIEFING DOCUMENT

REVIEW OF THE HEALTHTECH PROGRAM AFTER 18 YEARS

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TECHNOLOGIES FOR HEALTH: WHAT ARE THEY AND WHY ARE THEY NEEDED?

CIRCUMSTANCES IN DEVELOPING COUNTRIES

In many parts of the developing world, formal health services reach less than 50 percent of the population. Weak or no infrastructure, poor living conditions, limited individual and public resources, extreme environmental conditions, population growth, new migration patterns, wars and conflicts are only some of the challenges associated with the achievement of "health for all." While enormous gains have been made in improving health care for people in the developing world over the past quarter century, there have been significant setbacks in recent years. The AIDS pandemic, development of resistant strains of diseases, new migration patterns, continued growth in populations, climate change, decaying infrastructure due to lack of reinvestment, and many other factors bring new challenges.

Technologies are an essential component of the strategies to address these challenges. Even in circumstances of low infrastructure, sparse training, and limited management, well-designed and targeted technologies can catalyze change, modify harmful behavior, overcome impediments, increase access to care and treatment, and raise awareness of healthy practices. As conditions improve, technologies can accelerate and augment improvements in the health of populations.

The most pressing challenges that may be addressed through new technologies are life-threatening diseases unique to, or still prevalent in, many areas of the developing world. The specific means of prevention, detection and treatment of these diseases are often not available, affordable, or readily adaptable. Other challenges arise from limited choice and the need to enable voluntary practices that result in positive health outcomes. In family planning, for example, needs exist for adapted, effective contraceptive technologies that respond to individual and cultural needs and overcome environmental or economic constraints.

In some parts of the world, local health care approaches may involve practices that result in adverse health outcomes. While education and training are essential to long-term solutions, technologies to constrain or modify such behavior can have a highly positive impact in the interim. For example, reuse of syringes, a practice that is now known to be responsible for transmitting a significant proportion of bloodborne diseases, can be prevented through the use of auto-disable (AD) syringes.

Adverse environmental conditions or lack of infrastructure may also be overcome with technologies. For example, solar and alternative fuel refrigerators can be used where electricity from the grid is not reliable or available, and adapted motorcycles and cold boxes are used to deliver essential commodities to areas without road access.

Access to and effectiveness of health care services may also be addressed with the aid of technologies. Rapid diagnostic tests can permit early detection of conditions at the point of care, allowing treatment and counseling while the client is still in the clinic. The ability to detect and treat disease during one visit reduces the risk of loss to follow-up, as well as the burden on the client who may have traveled for many hours to reach a health center. Similarly, heat-stable and

multivalent vaccines, vaccine vial monitors (VVMs), prefilled injectors, and ice-free cooling can better ensure access through outreach and improve the efficiency and outcome of immunization programs. Advanced communication and data-management technologies can have a broad impact on the effectiveness and efficiency of primary health care programs and on strategic planning and implementation by all levels of health systems.

FAILURE OF MARKETS TO MEET THE NEEDS

Driven by changes in humanitarian aid budgets, significant progress toward self-reliance in many countries, and changing philosophies of development, international aid has shifted in recent years from donations of goods and services toward sustainable capacity building, financing, and use of market mechanisms. Markets depend upon the willingness of investors to risk capital in the development, scale-up, production, promotion, and distribution of goods and services that they believe others will buy at a margin above cost and upon others who perceive the goods to be of value and have money to spend on them.

If market forces can be harnessed successfully, they can be durable and self-reinforcing. However, market forces alone are insufficient for technologies to reach the health care priorities of resource-poor populations. For-profit enterprises are reluctant to design products and services for developing-country markets, fearing a poor return on their investments. In the industrialized countries, technologies have been focused largely on curative care, centralized services, elective procedures, and commercial delivery systems; these provide high profit margins and require large health care budgets and high levels of system infrastructure and practitioner skills. Since most health-related research and development is carried out in these wealthy countries, the resulting technologies have been suited to the prevailing conditions cultures, users, budgets, and demands of these societies.

In the developing world where budgets are severely limited, resources by contrast must be more focused on primary health care needs. Primary health care needs of resource-poor populations are generally served by typically poorly funded government-run public programs. These programs are focused on delivery of services but are often hampered by the absence of key technologies and the inappropriateness or high cost of others. Appropriate technologies must address the unique problems and withstand the difficult conditions of developing countries while remaining effective and low cost.

WHAT CAN DEVELOPMENT ASSISTANCE AGENCIES DO TO FILL THE GAP?

THE TECHNOLOGY CHALLENGE

The “technology” challenge for health development agencies and organizations is how to make appropriate, affordable, acceptable, and cost-effective health care technologies available for resource-poor populations. Supporting the design, development, scale-up, production and distribution of technologies solely through the public sector, however, is clearly beyond available resources and political will. In addition, it would not be likely to result in economically sustainable outcomes. Public investment in suitable technologies is indispensable, but must be programmed to catalyze private commercial investment through effective public/private collaboration.

THE ROLE OF THE "BRIDGING" ORGANIZATION

International agencies have therefore turned to organizations like PATH, a nonprofit agency that bridges the gap between the public and private sectors, and forges collaborations that benefit both. The HealthTech program at PATH has played this critical role of a bridging agent between the public development sector and health product industries in the private commercial sector. As a bridging agent, HealthTech introduces proprietors of relevant health technologies or processes in the commercial sector to the specific needs and constraints of developing countries and invites and encourages them to help create solutions. Commercial enterprises are constrained by the real and perceived risks and low margins associated with developing-world public health markets. To overcome these constraints, HealthTech must provide or identify real value, reduced risks, and demonstrated market potential. It does this by creating potentially valuable intellectual property, validating products on the bench and in the field, defining markets and introduction strategies, engaging with international "gatekeeper" agencies to adjust policies and best practices, and developing a value proposition that is meaningful to all the stakeholders who influence or enable change in developing-world primary health care programs.

EVOLUTION OF THE FUNDING ENVIRONMENT FOR HEALTH TECHNOLOGIES

USAID AS A PIONEERING DONOR IN THIS ARENA

Until the 1980s, support for new health technologies from public-sector international development agencies was focused primarily on family planning and a few vaccines. USAID had been investing in contraceptive technologies for many years and, in 1985, stimulated by the promise of the emerging biotechnology, launched an exploratory five-year program to develop new technologies called Diagnostics for Community Health (DiaTech), which was implemented and managed by PATH. Although there were no immediately accessible appropriate technologies from the emerging biotech movement at that time, the approaches and prototypical products developed during the first two years were sufficiently encouraging to USAID that they asked PATH to expand the activities to discover and advance a broader set of technological solutions to developing-world health problems. A new three-year cooperative agreement, named HealthTech: Technologies for Child Health, was designed to identify and advance technology solutions to priority developing-world health problems within the broad arena of USAID's health-related programming. In 1990, the two programs were merged into one, as HealthTech II: Technologies for Health cooperative agreement. The project was renewed in 1996 as HealthTech III, followed by a competitively bid RFA for HealthTech IV, which PATH bid on and won in 2001. HealthTech IV is now in its fourth year of a five-year cooperative agreement with USAID.

HEALTHTECH AS A CENTER OF INNOVATION

The broad scope, flexibility, and the continuous nature of the project enabled PATH to put together a broad portfolio of product development projects. At the same time, it allowed PATH to build capacity with the human and physical resources necessary to effectively undertake innovative research and development of health technologies specifically for low-resource settings. The original goals and objectives of the project in 1987 are still very valid today.

Goal: To improve the health status of less-developed country populations, particularly children.

Objectives:

- To develop a single-use vaccine injector, other immunization-related technologies, and products for other child survival interventions which are appropriate for field use in developing countries.
- To adapt these technologies and appropriate technologies developed elsewhere, for community health care practice by carrying out field trials, refinement activities, and production engineering, packaging, and other scale-up activities.
- To ensure that HealthTech technologies are produced and distributed by qualified manufacturers and other firms or organizations through the granting of licenses to manufacture, market, and distribute the products, and the provision of technical assistance and financing.
- To introduce the products arising from these developments, as well as appropriate products available from other sources, into public-sector health programs through information dissemination activities, including conferences, workshops, publications, training and demonstration materials, and test markets.

Over the years, PATH has developed and refined the methodologies and approaches necessary to advance devices and diagnostics from original design or adaptation of existing technologies through product development, bench and field testing, technology transfer, scale-up, licensing, product introduction, and market development. Multidisciplinary staff and teams have been assembled and trained including product designers, engineers, biotechnicians, scientists, public health specialists, economists, business development and commercialization experts, all of whom specialize in understanding the particular scenarios and methods of designing and introducing health technologies for developing-world settings. Guidelines for working with the private sector have been developed that focus on protecting the public sector's interests in affordability and availability (see Appendix 1). Practices for managing intellectual property for the benefit of both the private and the public sectors have been formed. Laboratory and shop facilities, dedicated to the purpose of developing and testing prototypes of devices and diagnostics under conditions that simulate the harsh environments of developing countries, have been assembled. Design control and regulatory systems have been established. Processes and systems for technology transfer to both developed- and developing-country manufacturers have been developed.

Through all of this, combined with portfolio management, HealthTech has successfully incubated and advanced multiple products over the years. Several products that are now distributed in the billions worldwide for immunization programs and detection of infectious disease were initiated during HealthTech I and II. For more information about PATH's methodologies, processes, and systems for product development, see the four HealthTech proposals and the final reports of the three completed HealthTech cooperative agreements, provided to the reviewers separately. Also, see the published article included as Appendix 2 for an in-depth discussion of the topic: "Achieving appropriate design and widespread use of health care technologies in the developing world. Overcoming obstacles that impede the adaptation and diffusion of priority technologies for primary health care." This article summarizes PATH's experience and knowledge on technology development for developing-world use as demonstrated through the 18-year history of the HealthTech program.

THE PORTFOLIO APPROACH TO ADVANCING TECHNOLOGIES

Portfolio management is described as:

> *". . . a dynamic process, through which a list of active R&D projects is constantly updated and revised. In this process, new projects are evaluated, selected and prioritized; existing projects may be accelerated, terminated or de-prioritized; and resources are allocated and re-allocated to the existing projects. The portfolio decision process is characterized by uncertain and changing information, dynamic opportunities, multiple goals and strategic considerations, interdependence among projects, and involvement of multi-decision-makers."*[1]

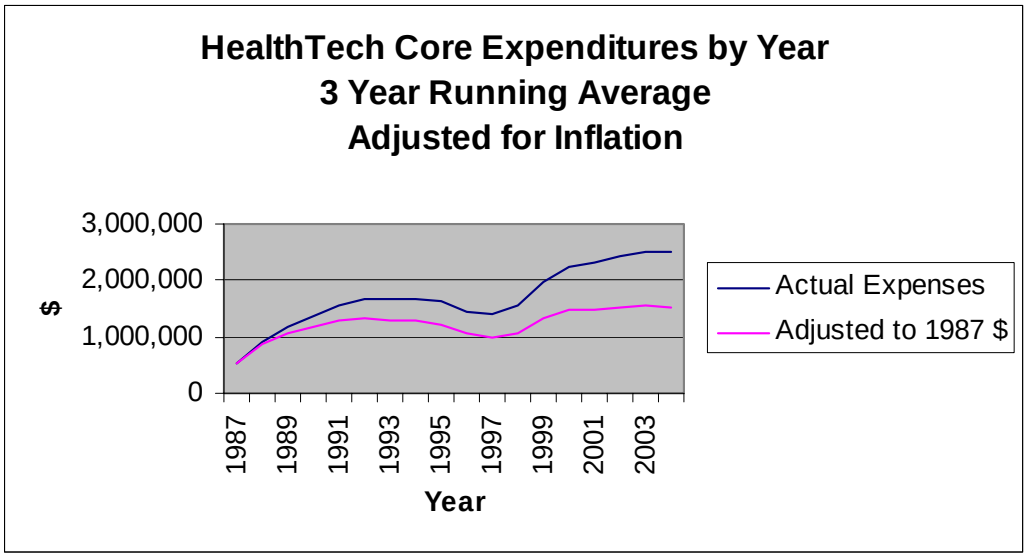
For more than two decades PATH has advanced a portfolio of products for developing-world health care focusing on neglected areas of need and on technology solutions to those needs that can be developed and introduced with moderate (<US$5M) investments of public money. (Technologies requiring larger investments, like vaccines, are also advanced at PATH but as individual projects with dedicated staff and resources.) The portfolio has been maintained through:

- Core funding, primarily from USAID through HealthTech.
- Cofunding from other donors willing to leverage their investments through the HealthTech lead.
- Small donors interested in contributing to specific technology projects.
- Other nongovernmental organizations (NGOs) and government organizations willing to carry out tasks (like clinical testing) on their own budgets.
- Commercial companies convinced to coinvest by taking on, scaling up, manufacturing, and distributing the products.

Core funding dollars from USAID in 1987 dollars have remained relatively flat over the years so that the portfolio has become more dependent on the other contributions (see Figure 1). However, the value of the core HealthTech support as a lead investment continues to be the key to attracting other investors.

[1] Pasek ZJF, Maghami AS. Linking strategic planning with R&D portfolio management in an engineering research center. 5th International Conference on Managing Innovations in Manufacturing, Milwaukee: 2002.

Figure 1.



The principal challenges of management of a portfolio of R&D activities for HealthTech are:

- Balancing the needs, strategies, expectations, and limitations of individual stakeholders/contributors with what is necessary to build and maintain a broad and deep inventory of creative skills, tools, and facilities.
- Maintaining the flow of incremental funding to keep portfolio projects moving at an optimal level and pace.
- Achieving balance among projects of various size, length, risk, and requirements for different facilities and skills.
- With limited unrestricted funding, developing convincing investment cases for new technology solutions.
- Maintaining sufficient flexibility of resource allocation and decision-making to take advantage of opportunities and to manage rapidly changing circumstances.
- Resource management to ensure adequate, timely application of skills to fulfill critical path deliverables.

There is a "critical mass" aspect to the maintenance of capacity to discover and advance innovations. It requires a delicate mix of vision, skills, motivation, tools, and experience to function effectively. As a nonprofit, nonendowed NGO, PATH is entirely dependent on donors for all its projects. USAID and the attendant cofunders have enabled PATH to develop a unique pool of talent with deep knowledge of all stages in the product value chain and product development process. The replacement value of this pool is very high and the replacement lead time is measured in years. This capability arguably represents a unique resource for the developing-world health care development community. We seek to preserve and grow this resource so that we can continue with our donor, and NGO and commercial partners, to find technology solutions for priority developing-world health care problems.

At the same time, we are committed to meet all of our obligations to our donors, to understand their strategies and constraints, and to harmonize our portfolio activities to their short- and long-term needs to the greatest extent possible. In this we rely on their understanding and appreciation of the means and conditions that foster innovation and enable new technologies to come about.

EIGHTEEN YEARS OF HEALTHTECH: RESULTS AND IMPACTS TO DATE

The scope and diversity of work under the HealthTech portfolio is extensive. In order to provide a sufficiently comprehensive yet readable account of results, we have provided summary tables, statistics, and lists below, all of which refer to fuller accounts in the appendices or supplementary documents.

IDENTIFICATION OF HEALTH NEEDS AND TECHNOLOGY SOLUTIONS

HEALTH PROBLEMS ADDRESSED VIA TECHNOLOGY SOLUTIONS

HealthTech's mandate from the beginning has been to identify needs in the fields of health, family planning, and nutrition in which technology can catalyze lasting solutions. Needs or challenges that are addressed by HealthTech teams have fallen into several categories, more or less aligned with USAID's strategic objectives. Examples of the range of problems and needs addressed by HealthTech and evidence of impact per strategic objective follow (see Table 1). More information about the health needs addressed appears on each Technology Update, sent to the reviewers in a separate binder entitled "Technology Solutions for Global Health."

Table 1. HealthTech Results and Indicators of Impact

NEED	USAID Strategic Objective (SO)	HEALTHTECH RESPONSE		CURRENT AND EXPECTED RESULTS AND IMPACT		
		Technology or Deliverable	Status	Policy Impact	Supply System Impact	Program Impact
Reduce vaccine wastage and increase immunization effectiveness.	SO 3	VVMs Materials for training and introduction of VVMs Also: Cold Chain Prefill unit-dose Uniject™[2] Autodisable syringes	In use	Facilitated change in the World Health Organization's (WHO) multi-dose policy that allows health workers to use opened vials of liquid vaccine for more than one day, up to one month. WHO and United Nations Children's Fund (UNICEF) issued joint policy statement in 1999 recommending use of VVMs on all vaccines. Required on all vaccines supplied by the Global Alliance for Vaccines and Immunizations (GAVI) Vaccine Fund. (353 million doses of hepatitis B, Hib, Yellow Fever, and combination vaccines since 2001).	Private-sector partner producing for global market through UNICEF. All vaccines supplied by UNICEF now require VVMs. Over one billion used on vials of vaccine as of 2004; US$137 million are purchased annually by UNICEF suppliers. 17 vaccine manufacturers now using on vaccines. Training materials available through WHO and PATH.	Vaccines now verifiably free of heat damage at time of vaccination. Extends the reach of vaccines beyond the cold chain. Millions of dollars are being saved by immunization programs and available for more vaccines or greater coverage due to lower rates of vaccine wastage. Improved vaccine stock management so health workers able to read and rely on VVMs effectively.
Decrease vaccine damage due to freezing in the cold chain.	SO 3	Freeze-proof vaccine refrigerators Cold chain assessment tools Information packets on protection of vaccines from freezing Extensive freeze research in field and lab	In the pipeline and in use	WHO adopted HealthTech's (HT) cold chain monitoring protocol and recommended it to all countries. WHO developing new policy and specifications that will create freeze-prevention strategies and require freeze-proof refrigerators. Government of Indonesia adopting new policies based on HT research (e.g., requiring water packs rather than ice packs; introducing new training programs).	Manufacturers of cold chain technologies for other purposes working with HT to adapt for use in immunization programs in developing countries. 7,000 training posters and training curricula disseminated to cold chain workers throughout Indonesia.	HT studies demonstrated high rate of freezing of vaccines (up to 100%) in the cold chain in several countries. Monitoring of cold chain post training and procedural changes has validated significant reductions in freezing of vaccines. Millions of patients now receiving vaccines in Indonesia, Vietnam, Afghanistan, and other countries are being effectively immunized with vaccines that have not been frozen in the cold chain due to new procedures

[2] Uniject is a trademark of BD.

NEED	USAID Strategic Objective (SO)	HEALTHTECH RESPONSE		CURRENT AND EXPECTED RESULTS AND IMPACT		
		Technology or Deliverable	Status	Policy Impact	Supply System Impact	Program Impact
Continued…						and training that increase the reliability and performance of the cold chain.
Reduce transmission of bloodborne diseases due to dangerous misuse of unsterile syringes and needles.	SO 1, 3, 4	SoloShot™[3] auto-disable syringe Facilitation of other AD syringes (e.g., Star and others) Uniject prefill injection device Screening/promotion of other auto-disable syringes Training manuals on "Giving Safe Injections: Using AD syringes" Safe needle removal/disposal Needle-free vaccine delivery	In use	In 1988 WHO held EPITECH meeting, the first call for safe injection devices, with HT assistance. 1997 WHO-UNICEF-UNFPA joint statement recommended use of AD syringes in immunization services. Current policy of all UN agencies that only AD syringes be used for immunization. WHO launch of safe injection website with HealthTech assistance. HT one of founders of Safe Injection Global Network, alliance of stakeholders and gatekeepers on injection safety issues.	Over 2 ½ billion SoloShot syringes had been supplied by BD to public health programs in 40 countries, mainly via UNICEF, by 2004. 13,000,000 AD syringes provided in 2004 are now being supplied to and used in the President's Emergency Plan for AIDS Relief (PEPFAR) programs in 11 African and Caribbean countries. GAVI Vaccine Fund has committed US$113 million to countries for injection safety support, including purchase of AD syringes and safety boxes. Licensee BD supplying Uniject to pharmaceutical manufacturers. Uniject with hepatitis B and TT vaccines already on the market. 43 million Uniject devices supplied by BD through 2004. Application of Uniject devices filled with gentamicin, oxytocin, and injectable contraceptives being investigated and developed by manufacturers.	Family planning programs supported by USAID throughout the world are receiving DMPA bundled with SoloShot syringes and instructions on safe injection practices. Millions of women and children worldwide have received immunization injections via SoloShot syringes, with assurance that they have not inadvertently been exposed to life threatening diseases in the process. Health workers in Mali, Afghanistan, and Ghana have safely and easily delivered 6.6 million doses of TT to women through the UNICEF tetanus elimination program. Multiple acceptability studies of Uniject devices have demonstrated that they are perceived to be easier to use for health workers.

[3] SoloShot is a trademark of BD.

NEED	USAID Strategic Objective (SO)	HEALTHTECH RESPONSE		CURRENT AND EXPECTED RESULTS AND IMPACT		
		Technology or Deliverable	Status	Policy Impact	Supply System Impact	Program Impact
Increase coverage with vaccines and life-saving medicines by enabling peripheral health workers to give safe injections.	SO 2, 3	Uniject prefill injection device	In use	Indonesian has adopted a national policy to provide a birth dose of hepatitis B vaccine in the Uniject device to infants born at home. First time that Ministry of Health (MOH) has authorized midwives to give immunizations, in part because of Uniject safety and ease of use features. Global maternal health experts at a 2003 meeting in Bellagio identified Uniject filled with oxytocin as a method for midwives to treat women for hemorrhage in third stage of labor.	43 million units supplied by BD to pharmaceutical companies primarily for use with vaccines by 2004. By 2001, 17 companies had conducted pilot fills of Uniject devices, and five had purchased filling lines. The first commercial product in the Uniject device became available in 2000. Today the following are available: hepatitis B vaccine and tetanus toxoid (TT) from P.T. BioFarma (Indonesia) and hepatitis B vaccine from Lab Pablo Cassara (Argentina), Shantha Biotechnics (India), and Panacea (India). Currently, more pharmaceutical companies are well underway in preparing to manufacture and market product in the Uniject device. Another company in Argentina is starting to conduct studies of gentamicin and oxytocin in the Uniject device.	5 million newborns a year in Indonesia are being easily and safely vaccinated by midwives against hepatitis B through use of Uniject, many of these are delivered in the home. Health workers in Mali, Afghanistan, and Ghana have safely and easily delivered 6.6 million doses of tetanus toxoid to women through the UNICEF-sponsored Partnership for Child Health for elimination of tetanus. Cost-effectiveness study in Indonesia demonstrates cost savings of Uniject with hepatitis B vaccine. Evidence from study in China that use of Uniject for delivery of hepatitis B vaccine increases coverage. Evidence from study in Vietnam of acceptability and cost-effectiveness of oxytocin in Uniject compared to use of vials, needles, and syringes
Increase acceptance of affordable options for injectable contraceptives.	SO1	1-ml Uniject prefill injection device	In the pipeline	USAID committed to supplying injectable contraceptives (DMPA) for USAID-supported family planning programs within the Uniject device, once available.	Primary supplier of DMPA for USAID programs has already invested over US$5 million in development program for DMPA filled in Uniject in anticipation of building capacity to supply international family planning programs with 30 to 50 million units of DMPA in Uniject per year. Will simplify packaging/delivery of DMPA by combining single-dose with injection system.	Will enable a new USAID strategy for delivery of injectable contraceptives in the field by minimally trained health workers and even home-administration.

NEED	USAID Strategic Objective (SO)	HEALTHTECH RESPONSE		CURRENT AND EXPECTED RESULTS AND IMPACT		
		Technology or Deliverable	Status	Policy Impact	Supply System Impact	Program Impact
Eliminate needlestick injuries and reduce cost and resupply burden of safe injection in small health centers.	SO 3	Needle free technologies Sharps waste disposal technologies Training materials WHO Sharps policy work	In the pipeline	Based on PATH inputs WHO determined final safety standards for multi-user jet injectors. WHO actively supporting next generation jet injectors for dose spacing.	Involved in formation of Association of Needle-Free Injector Manufacturers. Working with several manufacturers on different approaches. Will substantially reduce resupply system for syringes/needles.	Will provide systems for safe injection for immunization campaigns and simplified, safer disposal at a lower cost per immunization than needle and syringes. Studies show that reusable nozzle approach provides protection against transmission of bloodborne pathogens between patients.
Decrease unsafe disposal of used and potentially contaminated needles and syringes.	SO 1, 2, 3, 4	Sharps waste disposal technologies (multiple) - Needle removers - Syringe disablers - Pit or barrel disposal - Melting technologies Materials for training on waste disposal Also: Needle-free technologies	In use and in the pipeline	Influence on WHO policy development regarding needle removers. GAVI named needle-remover systems as top priority issue for research in 2003. 9 SEARO countries recommended needle removers as top priority in 2003.	Needle-removal devices now less expensive and more broadly available from 3 manufacturers. HT's design made available in the public domain. 2500 devices have been ordered for use in the PEPFAR programs in 11 countries in Africa and the Caribbean. 1000 devices ordered for demonstration programs in Senegal and Cote-d'Ivoire. 14,000 devices ordered by the state of Andra Pradesh in India.	Health workers in Senegal, India, and Uganda find needle removers to be an acceptable method to prevent sharps injury and reuse, and to dispose of infectious sharps waste.
Decrease problems with the cold chain by eliminating the need for it altogether.	SO 3	Vaccine stabilization technologies	In the pipeline	Recognized by GAVI as one of three priority technologies for R&D to improve the effectiveness and efficiency of immunization programs.	Manufacturers working on feasibility studies with PATH. HT investment leveraged by large grant from private foundation donor.	Will improve immunization effectiveness through prevention of heat and freeze damage to vaccines. Gains in efficiency through reduction of wastage due to temperature damage to vaccines, lower shipping and storage costs, decreased logistical and equipment requirements, and longer shelf lives.

NEED	USAID Strategic Objective (SO)	HEALTHTECH RESPONSE		CURRENT AND EXPECTED RESULTS AND IMPACT		
		Technology or Deliverable	Status	Policy Impact	Supply System Impact	Program Impact
Enable women to protect themselves with barriers.	SO 1, 4	Woman's Condom SILCS Diaphragm	In the pipeline	UNAIDS, USAID, and country programs integrating additional options for women into reproductive health program strategies.	International commercialization groups conducting due diligence prior to technology transfer.	Unprecedented user satisfaction with device performance will result in more protected sex and lower rates of unwanted pregnancy and disease transmission, particularly among most vulnerable populations who have very limited options currently.
Provide less expensive, easier, quicker methods for screening populations for vitamin A deficiency.	SO 3	Retinol Binding Protein-Enzyme Immunoassay (RBP-EIA)	In use	Presented results of studies at International Vitamin A Consultative Group meeting in 2004 where interest was high. Study in Thailand using RBP-EIA test showed the first evidence of the biological comparability between serum retinol levels estimated from venous blood and capillary blood. Adds to evidence of close correspondence between retinol in venous blood samples and RBP in capillary blood.	Know-how transferred and licensed to private-sector company and available for use by monitoring and evaluation and surveillance programs.	Method of screening that provides rapid, quantitative results; reduces reliance on centralized laboratory facilities; and can reduce the need to transport specimens to developed countries for analysis. Facilitates easier and less expensive screening of populations, leading to program decisions about interventions. Reduction in cost of vitamin A determination from US$20.00+ to < US$3.00.
Improve diagnosis of HIV/AIDS and surveillance of the blood supply which is inadequate due to high cost and complexity of available diagnostic tests at the point of care.	SO 4	Rapid, low cost dipstick test for HIV-1 and HIV-2	In use	Independently evaluated at the WHO Collaborating Centre for AIDS; sensitivity was 99.5% and specificity was 98.2%. WHO's HIV evaluation program at the Institute for Tropical Medicine in Belgium has evaluated the HIV dipstick test from PATH's collaborators as well as other rapid/simple tests. As a result, WHO policy has evolved to include the use of rapid tests for diagnosis of HIV.	Licensed to manufacturers in developing countries; 3 in India, Indonesia, and Argentina, are still producing and selling tests regionally and globally. Local production and supply simplifies logistics and reduces costs. Availability of PATH HIV dipstick stimulated the market. Many more low-cost, rapid tests are now available in developing countries.	15,300,000 tests in Asia and South America for HIV/AIDS have been sold and used, allowing quick and easy identification of HIV in the blood supply and in case management. Cost of dipstick 30% to 70% less than commercial tests available at that time in developing countries. The prices of tests dropped by 50% to 50 cents per test making it much more affordable for low-resource populations.

NEED	USAID Strategic Objective (SO)	HEALTHTECH RESPONSE		CURRENT AND EXPECTED RESULTS AND IMPACT		
		Technology or Deliverable	Status	Policy Impact	Supply System Impact	Program Impact
Improve diagnosis of sexually transmitted infections which is inadequate due to high cost and complexity of available diagnostic tests at the point of care.	SO 4	Rapid, point-of-care tests for gonorrhea (GC) and chlamydia	In pipeline	Sexually Transmitted Disease (STD) Diagnostics Initiative at WHO has encouraged development and advancement of new tests. WHO included PATH's GC test in a comparative evaluation of GC tests in Benin.	GC test licensed to manufacturer in India, which is currently undertaking further sensitivity and manufacturing improvements of the test and preparing for production. The product will soon be marketed. Same licensee is interested in Chlamydia test.	The gonorrhea test developed by PATH, which demonstrated 70% sensitivity and 97% specificity in a WHO-sponsored trial in Benin, is one of the first successes for a rapid test in improving diagnosis for this difficult disease. Will enable testing for GC to be carried out at point of care in peripheral health centers. Enable expanded testing beyond reference laboratories, including testing of patients at antenatal and STD clinics Provide same day results, allowing for immediate and appropriate treatment thus reducing loss of patients to follow-up.
Reduce morbidity and mortality from syphilis.	SO 2	Rapid, easy test for syphilis.	In use	HealthTech is working with WHO and the STD Diagnostics Initiative to develop a consensus document on the laboratory methods for evaluation of rapid syphilis tests.	Syphilis test transferred to one UK, one Indian, and one American manufacturer; technical assistance provided to one Indian manufacturer. Syphilis test being sold and used (statistics not available).	Centers for Disease Control and Prevention (CDC)-sponsored study showed positive results for American manufacturer's test. Enables expanded testing beyond central testing laboratories, including testing of expectant mothers at antenatal clinics. Provides same day results, allowing for immediate and appropriate treatment thus reducing loss of patients to follow-up.

NEED	USAID Strategic Objective (SO)	HEALTHTECH RESPONSE		CURRENT AND EXPECTED RESULTS AND IMPACT		
		Technology or Deliverable	Status	Policy Impact	Supply System Impact	Program Impact
Reduce mortality from malaria by early and accurate diagnosis.	SO 5	Falciparum Malaria EIA Rapid, easy falciparum malaria test	Not in use In use	HealthTech has worked with WHO/WPRO to develop documents and guidelines for expanded use of and quality control in production of rapid malaria tests.	Technology transfer to companies in India and Germany for sale globally. Technical assistance provided to one Indian, one South African, and one UK manufacturer.	Approximately 10,500,000 tests had been sold and used by 2004. Replacement or supplemental method to microscopy; enables expanded testing beyond specialty clinics. Provides same day results, allowing for immediate and differential treatment for falciparum vs vivax malaria, thus saving cost of drugs, reducing morbidity/mortality, and reducing loss of patients to follow-up.
Reduce transmission of hepatitis B through contaminated blood.	SO 5	Hepatitis B rapid test	In use	Rapid tests for hepatitis B may allow India and Indonesia to change their testing policy to include use of rapid tests at either clinics for diagnostics of patients or at lower levels of the blood bank system.	Technology transfer to companies in India and Indonesia, where they are being produced and sold	Over 4 million had been sold by the companies by 2004. Enables screening for hepatitis B by smaller or rural blood banks that cannot sustain use of higher-volume EIA methods. Provides same day results, allowing for immediate removal of contaminated blood and use of uncontaminated blood if needed.
Decrease incidence of neonatal tetanus and puerperal sepsis.	SO 2	Clean home delivery kits Guidelines for setting up local production of delivery kits	In use	Quantitative study by HealthTech of kit use (enrollment of 3,262 pregnant women in Tanzania) demonstrates positive correlation between kit use and reduction in cord infection and puerperal sepsis. Nepal kit endorsed by national government.	Maternal Child Health Products producing and selling kits in Nepal, with HealthTech assistance. Sales were 850,000 kits through 2004, providing income to the women-owned cooperative. Sustainable local supply also in place in India and Bangladesh.	Training for local assembly quality assurance and marketing results in income-generating business, as well as health benefits of locally appropriate delivery kits. Study results can be used by program managers and donors for decision-making about investing in delivery kit projects. Basic delivery kit guide published in collaboration with WHO and disseminated to maternal child health managers worldwide.

NEED	USAID Strategic Objective (SO)	HEALTHTECH RESPONSE		CURRENT AND EXPECTED RESULTS AND IMPACT		
		Technology or Deliverable	Status	Policy Impact	Supply System Impact	Program Impact
Enable detection and appropriate care of low-birthweight newborns.	SO 3	BIRTHweigh scale (I, II, and III)	In use	BIRTHweigh I approved by WHO.	Distributed through the UNICEF catalog since 1991 as BebeWey. At least 80,000 units have been sold by UNICEF since 1991.	Scale designed for nonliterate traditional birth attendants that allows for yes/no identification of low birthweight. Being redesigned for use in determining proper dosage of gentamicin for neonatal infection. Studies showed high acceptability, ease of use, and transportability.
Improve detection of anemia.	SO 3	Visual anemia scale Manuals on anemia detection devices	In use	WHO requested assistance from HT in assessing current device and manufacturing strategies. HT gave them the know-how.	Improved system now available through UNICEF catalog as hemoglobin color scale. Manuals translated, reprinted, and disseminated by global USAID nutrition program.	Anemia detection methods have evolved and improved with HealthTech's contributions.

TECHNOLOGIES IN THE PRODUCT DEVELOPMENT PIPELINE

The following statistics summarize the numbers of HealthTech technology activities over the 18-year history that have been undertaken to address these needs:

122 technology ideas have been investigated under HealthTech.

45 technologies were screened out after initial consideration.

38 technologies were developed or are being developed at PATH under HealthTech, and **21** that were adapted from existing technologies or codeveloped with other entities.

18 subject inventions have been reported to USAID; **9** patents have been applied for; **5** patents have been granted; and **3** awards have been received for innovative technologies developed at PATH.

55 technologies or technology fields were advanced by HealthTech, including collaborations with private-sector companies on their own technologies.

155 field evaluations of **57** different technologies were carried out in **53** countries.

63 technology transfers to commercial partners for **21** different technologies have been conducted.

26 technologies have been commercialized.

19 technologies are currently known to be sold and in distribution globally or regionally, for a total of **3.8** billion units sold.

A full list of the technologies that have been investigated and/or pursued in the last 18 years, organized by health sector and areas of expertise at PATH, appears in Appendix 3.

FIELD STUDIES/EVALUATIONS BY HEALTHTECH

During the course of product development, technologies are usually taken to the field to be assessed under the typical developing-world conditions and in the hands of potential users. During early stages, prototypes of the technologies are used in design-stage field trials, where the data collected feeds into the design process. Later more final versions of the products are evaluated for effectiveness, acceptability, and operational impact under challenging conditions representative of the target populations. Sometimes these studies are focused on existing technologies to evaluate their practicality or feasibility in developing-world settings. In this case, suggestions for redesign of the products to make them more appropriate are provided to the manufacturers. Other groups—NGOs, universities, or agencies—are also encouraged to test late-stage prototypes independent of HealthTech. These third-party evaluations benefit the program by providing independent validation of the products, building awareness for eventual diffusion of the products, and leveraging HealthTech resources.

During HealthTech, more than 155 field evaluations have been carried out in 53 counties. To demonstrate the breadth and depth of HealthTech's involvement and integration into health systems in developing countries, a list of the locations and nature of many of these evaluations appears in Appendix 4.

ECONOMIC EVALUATIONS AND MARKET STUDIES

A related step in the development process is often to evaluate the expected cost impact and cost/benefit analyses of new technologies relative to the costs of existing technologies. This information is vital to present to decision-makers and program managers responsible for procurement of technologies and is used in various ways. Similarly, market studies and marketing information is needed to provide commercial companies with credible data on the scale and drivers of these unfamiliar markets. Economists and market analysts have been added to HealthTech staff in the last ten years and have developed several whole-system approaches to the determination or projection of benefit attributable to a specific technology.

A list of economic and market studies attached as Appendix 5. In the past ten years, as the cost and complexity of diffusing new technologies for developing-world health care have become more evident, and where resources were available, projections of cost and benefit have been used to develop investment cases to support donor investment. For technologies at the introduction stage, analysis of actual costs and benefits from pilot sites or early adopter markets have been used to develop the value proposition that is then used to encourage uptake of the product by early mainstream users in programs and governments.

Many of these studies are published as a means of spreading information and encouraging uptake of the technologies. These published studies, most of which are in peer-reviewed journals, are included in the list of HealthTech publications (Appendix 6).

DATA ON WIDESPREAD DISSEMINATION AND USE OF TECHNOLOGIES

PRIVATE COMMERCIAL AND PUBLIC-SECTOR COLLABORATIONS

As described in sections of this document, throughout the history of the program a fundamental premise of the HealthTech is dependence on partnerships with public and commercial organizations to conduct its work. Approximately 95 commercial-sector partners have worked with HealthTech over the 18 years, sometimes as codevelopers from the very beginning of a project idea, sometimes as licensees after PATH has developed a technology to the point of needing a manufacturer, and sometimes as collaborators working together on a class of technologies. The full list appears as Appendix 7.

Specific information about commercial technology transfer recipients, licensees, and status can be found on the list in Appendix 8, in the accompanying Technology Updates Booklet and in the historical profiles of specific technology development tracks which will be provided to the reviewers during the site visit to PATH in Seattle.

HealthTech's involvement of public-sector partners is also extensive. Working closely with various divisions of WHO, UNICEF, CDC, GAVI, ministries of health, and bilateral agencies, HealthTech staff has played a critical role in defining global policies and guidelines related to

technologies, procurement, systems, and training. In-country work has often been directly in collaboration with ministries of health on similar issues at the national level.

HealthTech has also collaborated with at least 55 other entities including NGOs, USAID cooperating agencies, universities, research institutions, and local organizations on field evaluations of technologies and related activities. The breadth and variety of these partnerships can be seen in Appendix 9.

STATISTICS ON SALES, DISTRIBUTION, AND USE OF TECHNOLOGIES

One available measure of the success and the impact of the use of some technologies developed or advanced by HealthTech are the reports of worldwide sales in developing countries. For this, PATH relies on both formal and informal reports from the licensees and buyers of technologies advanced by HealthTech. The following table includes information on validated sales information up to 2004, where data is available to PATH (see Table 2). In addition, several HealthTech technologies are listed in the UNICEF catalog, which serves as a clearinghouse for multiple health technologies ordered by ministries of health and country programs throughout the world. Although sales data are not readily available for these technologies, there is evidence that they have been ordered and globally distributed. These include BIRTHweigh I (BebeWey) (reports of 70,000 distributed by UNICEF in early nineties), hemoglobin color scale, Sensor weighing scale for mothers and infants, and AD syringes.

Table 2. Data on Global Sales of HealthTech Technologies

Technology	Year*	Years Sold	Manufacturer	Units Distributed and Used as of 2004	Known Distribution
Vaccine Vial Monitors	1989	1996–current	TempTime (US)	1,202,983,285	Worldwide (mandated on all UNICEF/GAVI vaccines)
Uniject Device (Sales of empty Unijects to pharmaceutical and vaccine producers for multiple medicaments: hepatitis B, TT, combination vaccines, oxytocin, gentamicin, and DMPA)	1996	1998–2004	BD (US)	53,148,000	Mexico (1.2 M); Mali, Ghana, Afghanistan (9 M); Argentina (1.8 M; India (1.6 M); Indonesia (37.7M); Other (.7M).
SoloShot (SyringeLock) Syringe	1990	1992–2004	BD (US)	2,500,000,000	Worldwide
TB Dipstick	1994	1999–2004	Mossman & Associates (US)	1,879	n/a
Delivery Kit	1995	1995–2004	Maternal and Child Health Products (MCHP) (Nepal)	845,793	Nepal
Rapid Test for Pregnancy (original immunochromatographic strip [ICS] test platform)	1997	1999–2004	Advanced Micro Devices (India), Orchid (India), and Otsuka (Japan)	31,094,210	Worldwide
Rapid Test for Malaria	1998	1998–2002	Orchid (India), SPAN Diagnostics (India), Human (Germany)	10,500,000	Worldwide
Rapid Test for Hepatitis B	1998	1998–2004	J. Mitra (India), Orchid (India), YHS (Indonesia)	4,118,000	Worldwide
Rapid Test for Diphtheria	2003	n/a	Orchid (India)	n/a	Sales Pending
HIV Dipstick	1995	1995–2004	Wiener Labs (Argentina), SPAN Diagnostics (India), Yayasan Hati Sehat (Indonesia), BRIA (Thailand)	12,378,000	Worldwide

* Year collaboration began or year of technology transfer.

STIMULATION OF INDUSTRIES AND CATALYTIC IMPACT

One major outcome of HealthTech's work in developing and advancing technologies has been the impact on prices of competitive technologies, once the program makes a low-cost option available. Additionally, HealthTech's work on certain products has had a wider influence on an entire industry to the benefit of public health care services in developing countries. There are multiple examples of this over time including:

- In the early 1990s, under funding from HealthTech and the Edna McConnell Clark Foundation, PATH began a project to make low-cost reagent test strips available for determining hematuria in the urine for indirect diagnosis of Schistosoma haematobium infection. Hematuria test strips were already available but at prices too high for developing-country use. After developing a test strip for proteinurea (protein in the urine), PATH had capability to develop hematuria test strips based on the same core technology. As part of the project, PATH conducted laboratory analyses of existing hematuria test strip brands and obtained competitive price quotations from the manufacturers. This information was distributed to public-sector agencies for purchase decision-making. The competitive bidding resulted in a drop in prices from US$0.20 a test to US$0.02–US$0.11 per test. Since the goal of achieving low-cost strip tests had been reached, HealthTech concluded development of a new test strip.
- Another example of HealthTech's influence on pricing was the effect of the introduction of the HIV dipstick. In 2000 it was still the lowest-priced test kit for HIV-1 and HIV-2 on the market in India, Indonesia, and Thailand. The introduction of the HIV dipstick in the early 1990s at approximately US$0.50 per test was significantly less at that time than the cost of competing HIV tests at several dollars per test. This cost advantage contributed to its wider availability throughout the region and led to introduction of other rapid and less expensive HIV tests. PATH also evaluated and published the first evidence that two different rapid tests could be used in tandem to screen for and confirm HIV infection with accuracy comparable to HIV enzyme immunoassays and Western Blot tests, therefore reducing the need for more expensive, complex, and less-accessible tests. This principle of using two rapid tests was subsequently validated and expanded on by Family Health International and WHO, and was endorsed by WHO as an acceptable practice.
- HealthTech's concerted efforts to make AD syringes readily available for developing-country programs has paid off. The average price of a 0.5 mL AD syringe has dropped from US$0.12 to less than US$0.05 and is currently within one cent of the price of a disposable syringe. The introduction of the SoloShot syringe initially stimulated the industry and provided a high-capacity, well-capitalized global provider to withstand the prolonged period of market development and to respond to high-volume central procurement demands. Encouragement of other designs leading to local production and global competition provided a broad network of suppliers/promoters and a strong downward force on prices. It also introduced designs and opened up the market for curative injection safety.
- HealthTech has had a broad impact on the jet injector industry, helping it to evaluate new designs, developing new test methods focusing on safety, and leading a policy dialog with WHO and other normative organizations.

- Healthtech has made industry-wide assessments of needle destruction and needle-cutting technologies, providing feedback to manufacturers, and suggestions for redesign and cost-cutting.
- HealthTech has played a lead role in incubating the point-of-care diagnostics industry in India. It has transferred seven technologies to four manufactures, assisted two others to launch products, facilitated the launch of a components producer to supply the industry, helped secure international validation of products, and held seminars to raise public and private awareness of the value of point-of-care testing.

INFLUENCE ON POLICY ENVIRONMENT AND ISSUES

A key aspect of HealthTech's work is understanding the policy environments into which technologies will be introduced, especially technologies that will impact current practices. HealthTech has undertaken a substantial advocacy role in order to be influential and instrumental in changing the policies and best practice guidelines of the international health agencies and ministries of health. This can often take years. To do this, HealthTech has to retain technical depth, global vision, diplomatic skills, and a well-established record of constructive involvement. HealthTech has earned a basis of trust and continues to be invited to participate in WHO and UNICEF deliberations, frequently as the only NGO at the table.

To further policy objectives, HealthTech has also assisted WHO in the drafting of policy, guideline, and training documents (e.g., for safe injection; use of VVMs; multi-dose vial policy; prevention of freezing). HealthTech staff also drafted the first version of WHO/Expanded Programme on Immunization (EPI) safe injection website and is drafting model technology investment case guidelines for GAVI. HealthTech has also made significant contributions as founder, officer, or active member of a number of global forums on technology-related health issues. Among the most significant examples are:

- Organizer and participant in the first EPITECH meeting held at WHO where AD syringes were first discussed. This crucial meeting launched a drive toward safe injection technologies. PATH analyzed, organized, and then presented several designs.
- Cofounder of the Safe Injection Global Network (SIGN) with secretariat housed in WHO. SIGN has had a major influence on national policies for safe injection. SIGN also convinced the US Congress to include a safe injection component into PEPFAR, which is now introducing safe injection and sharps waste management practices for preventative and curative services into 14 countries.
- Initiator of the Technology Introduction Panel (TIP) in 1989—annual meeting of WHO, UNICEF Supply Division, USAID, and PATH. Recently revived as the Technology Operations Panel (TOP). These forums were designed to stimulate discussion and planning for upcoming introduction of new technologies
- Invited and active participants in annual meetings of Technical Network for Logistics in Health (TECHnet) and various subcommittees organized by WHO and exploring technical issues at the operational level of immunization programs

- PATH staff members currently serve on three WHO Performance, Quality, and Safety Working Groups—Temperature Monitoring, Refrigeration, and Safe Injection Technologies. The purpose of the working groups is to review specifications and test procedures for technologies.
- Appointed member of GAVI Task Force on Technologies. HealthTech staff served to define priority technologies for support by GAVI and The Vaccine Fund.
- Participated in numerous VVM meetings hosted by WHO and UNICEF and also attended by vaccine suppliers and potential VVM producers
- Cofounder and first secretariat of the Sexually Transmitted Diseases Diagnostics Network. (Secretariat transferred to WHO/Tropical Disease Research (TDR) in the early 1990s as the STD Diagnostics Initiative) The STD Diagnostics Network was designed to raise policymaker and donor interest in the need for more effective tests for reproductive tract infections.
- Participation in invited workshops at Bellagio, Italy, on (1) intellectual propery management for public health projects, (2) issues around maternal mortality, and (3) innovation systems.
- Participation in the annual International Vitamin A Consultative Group Meetings in Guatemala, Morocco, and Peru in the past few years.
- Active participation in committees of the International Standards Organization (ISO) on Latex Condoms and Jet injectors. These committees set global standards but are usually dominated by industry. PATH/HealthTech participation has raised awareness and brought about changes of relevance to primary health care and low-infrastructure environments.

DISSEMINATION OF INFORMATION

TRAINING MANUALS AND GUIDELINES PRODUCED AND DISSEMINATED

In the course of its work on technologies, HealthTech often develops appropriate training and information dissemination materials that have been widely distributed. These are listed in Appendix 10 and appear elsewhere in this report where they can be considered products themselves.

PUBLISHED PEER-REVIEWED ARTICLES BY PATH AUTHORS

As a key part of strategy to disseminate information on needs and technologies, build the evidence base, and encourage further uptake of validated products, HealthTech work has been submitted for publication in peer-reviewed journals. Since 1989, over 60 articles by PATH authors have been published. These include topics ranging from the results of laboratory and field evaluations of technologies to reports on identified needs and problems that lend themselves to technology solutions (such as freezing of vaccines in the cold chain) to discussions of the use of public- and private-sector partnerships devoted to the development of technologies for low-resource settings. See Appendix 6 for a complete list of publications.

LITERATURE CITATIONS ON HEALTHTECH TECHNOLOGIES

As HealthTech technologies have become more widely known and available, other organizations and entities have started to use or cite them in various systems and contexts. Evidence of this increase in attention to these products can be found in peer-reviewed literature, on website references, and discussions outside of PATH and HealthTech. An analysis of such references appears in Appendix 11 and attests, in an informal way, to the increasing awareness and support of these technologies by external parties.

HEALTHTECH PARTICIPATION IN OTHER USAID PROGRAMS

Another significant outcome of HealthTech's work as a center of expertise and innovation on developing-country health technologies is HealthTech's substantial involvement in related USAID projects. On many occasions USAID staff has turned to HealthTech to participate in technology-related work, both through centrally funded projects in Washington, DC, and through USAID mission-funded programs. This involvement has ranged from evaluation of technologies developed by others to participation in policy debates and discussions on technology-related topics, refinement of technologies, and provision of technical assistance in the field.

Of particular note is the significant role that HealthTech staff have played in the implementation of the PACT/CRH project in India, which has become a major site of production of HealthTech-generated technologies.

PROGRAM FOR THE ADVANCEMENT OF COMMERCIAL TECHNOLOGY/CHILD AND REPRODUCTIVE HEALTH (PACT/CRH), INDIA

Increased commercial-sector involvement is necessary for the introduction and correct use of high-quality child and reproductive health technologies. PATH staff in India and HealthTech staff from Seattle have been providing technical assistance to PACT-CRH, a ten-year, multimillion dollar program that promotes the health and nutrition of the Indian people. PACT-CRH is funded by the USAID Mission in India and is managed by the Industrial Credit and Investment Corporation of India. Underway since 1996, the program promotes ventures that develop products and services related to child survival; the provision of contraceptives; and the prevention of STDs, including HIV.

PATH's primary role in PACT-CRH has been to provide technical assistance related to the introduction of new technologies, including ones designed and developed under HealthTech. As of August 1998, additional field support was provided to PATH through HealthTech by the USAID Mission in India in support of this project. Activities since 1996 have included:

- Facilitated transfer or use of ten different technologies from the HealthTech project which are now made or used in India, including six point-of-care diagnostics tests, AD syringes, sharps disposal technologies, hepatitis B vaccine in the Uniject device, and VVMs.
- Reviewed and assessed sharps disposal technologies. HealthTech/PACT funding significantly accelerated the design review and commercialization timetable for the needle puller.
- Identified a US source of vaccine preservation technology and facilitated negotiations between the source and a major Indian vaccine manufacturer.

- Provided technical assistance on Good Manufacturing Practices (GMP) to several manufacturers.
- Provided technical assistance on condom manufacturing in several different areas, including specifications for packaging and production.

This work has directly impacted the health products industry in India, as noted earlier in this report.

PRESIDENT'S EMERGENCY PROGRAM FOR AIDS RELIEF (PEPFAR)

HealthTech's work in designing, developing, and advancing versions of AD syringes and technologies for dealing with the disposal of needles and syringes provided a technology "tool box" for the 2003 announcement of the allocation of US$15 million for safe injection interventions under PEPFAR. The global alliance known as SIGN, cofounded by HealthTech, was instrumental in raising the safe injection issues with the US Congress and bringing about the safe injection component of the PEPFAR initiative.

HealthTech staff are now involved in introducing safe injection technologies to all the PEPFAR countries under a subagreement with the prime contractor, John Snow, Inc.

LEVERAGING OF USAID FUNDS

One of the challenges of HealthTech has been the limited budgets that are available to accomplish full product development. In the commercial sector, companies spend millions of dollars bringing a product to market. HealthTech has not had the resources to be able to directly support that level of investment. In lieu of that, HealthTech has successfully leveraged its resources through partnerships and cofunders and by attracting commercial investment in the project through technology transfer, codesign or other value-adding collaborations. Overall, it is estimated that USAID funds have been matched at a ratio of two dollars of coinvestment to every one dollar of USAID support (US$72,121,000 of coinvestment matching US$36,068,000 in USAID support).

PRIVATE-SECTOR COINVESTMENTS IN TECHNOLOGIES

The following table presents data on known and verified in-kind investments by commercial-sector companies in the specific technologies they have licensed from PATH (see Table 3). Other companies, especially the manufacturers of HIV dipstick and the ICS tests for infectious diseases have invested their own and in-kind contributions as well, but these numbers are not verifiable at this time so are not presented here. These investments represent a ratio of private-sector investment to every dollar of USAID funds in the HealthTech program overall. For particular technologies, the ratio of leveraged funds is far greater.

Table 3. Private-Sector Investments in HealthTech Technologies

Technology	Year*	Manufacturer	Commercial Investment	USAID Investment	Dollars of Investment per USAID Dollars
Vaccine Vial Monitors	1989	TempTime (US)	$1,450,000	$1,072,000	1:1
Uniject Device	1997	BD (US)	$35,000,000	$3,282,817	10:1
Uniject for Injectable Contraceptives	2003	Pfizer (US)	$6,000,000	$335,445	18:1
Needle-Free Injector	2003	Felton International	$600,000	$563,414	1:1
SoloShot (SyringeLock) Syringe	1990	BD (US)	$15,000,000	$208,000	75:1
TB Dipstick	1994	Mossman & Associates (US)	$200,000	$182,000	1:1
Delivery Kit	1995	MCHP (Nepal)	$65,000	$759,000	1:10
HIV Dipstick	1995	Wiener Labs (Argentina)	$329,000	$363,000	1:1
TOTALS			$58,644,000	$6,765,676	9:1

* Year collaboration began or year of technology transfer.

COFUNDING BY OTHER DONORS DURING HEALTHTECH

Cofunding by other donors has also been a major source of funds for PATH to be able to accomplish the goals of developing and advancing many of these projects. For a full list of cofunding per technology, see Appendix 12. Below is a list of the major examples where cofunding for HealthTech projects was significant or exceeded the USAID dollars (see Table 4).

Table 4. Donor Cofunding for HealthTech Technologies

Technology	Cofunding From Other Donors	USAID Investment in HealthTech	Ratio of Cofunding to USAID Dollars
Uniject injection system (DMPA, Cyclofem, TT, hepatitis B vaccine, oxytocin, gentamicin)	$1,570,652	$3,616,535	1:2
Medical waste system technologies (Remover, Burner, other)	$504,572	$1,628,283	1:3
Cold chain system technologies (refrigerators, freeze studies, other)	$603,155	$866,325	1:1
Rapid syphilis test	$710,798	$696,553	1:1
Rapid gonorrhea test	$380,147	$1,489,509	1:4
Needle-free injector	$1,764,425	$563,414	3:1
BIRTHweigh birth weight scale	$319,000	$453,801	1:1
Dipstick test for HIV	$819,000	$362,887	2:1
Vaccine stabilization	$2,259,307	$285,371	10:1
Woman's condom	$1,368,517*	$132,325	10:1

* Does not include significant funding from USAID through the CONRAD program.

OVERARCHING ISSUES AND LESSONS LEARNED

LONG-TERM VISION

Since product development timelines are measured in years, it is necessary to be forward looking in the process of selecting and prioritizing development projects. Over years, critical changes can occur in the target groups of beneficiaries, service delivery programs, health priorities, and donor preferences. Technological advancements or other technologies can come into play which can affect all of these factors or provide better solutions to the target problem. Long-term vision of future needs is required. Paradoxically, focus on the future can put the program at odds with the present, e.g., the need for nonreusable syringes and medical waste technologies which was anticipated by HealthTech in the mid 1980s was undervalued until late 1990s when several studies demonstrated the impact of needle reuse on HIV transmission. As a consequence, at first donors and collaborators were not encouraged to invest in the development of the remedial technology. Most technologies in the HealthTech portfolio have encountered some degree of skepticism about the priority of the problem during the early part of development. This has become less of an issue as more of the technologies have been taken up or endorsed by international agencies and developing-world governments.

NEED TO SELL THE VALUE PROPOSITION

A related trend is the increasing demand by donors prior to investment for a detailed investment case with cost-benefit assessments and market metrics. In the absence of unrestricted funding, it becomes necessary to "sell" the value proposition of technologies, often with limited data. Intuitive assessments supported by expert opinion from relevant sources are often all that can be done ahead of donor support. Once start-up funding is available, early development and continual updating of the value proposition is crucial. For some technologies, proof of principle or early prototyping or modeling for human factors can be carried out in a short time at moderate cost. Use of these early prototypes to assess acceptability and value to potential users and stakeholders, often through demonstrations or evaluations in the field, can provide high-quality data. The cost and value of extensive conceptual market studies early in the project should be balanced against the estimated cost of early feasibility and prototype development leading to more meaningful market studies based upon actual show/touch/tell.

Product development pipelines can be very long, and iterative. R&D for the type of technologies advanced by HealthTech can take four to eight years at the scale of operation afforded by the level of portfolio funding achieved to date. Achieving widespread use can take much longer. While start-up, partial or incremental funding does not achieve the shortest development timeline, it has been successful in HealthTech because it attracts cofunding and commercial collaboration. Based upon the track record of the Healthtech portfolio, donors and partners can have confidence that the project will move forward with a reliable prospect for delivering the product.

Recently, USAID has become less tolerant of start-up commitments that rely on unidentified future investments to complete the project. Government mandates and budget cuts are resulting in a demand for short time-horizon, start-to-finish projects. Agency managers are becoming more reluctant to start projects that rely on additional future investments and promise deliverables

beyond the current funding period. Continued start-up and incremental funding for longer-term development projects will be necessary if the HealthTech portfolio is to be sustained. HealthTech has demonstrated that USAID has served as a catalyst for numerous projects that eventually were developed with multiple funding sources. Major examples include the Uniject device, SoloShot syringe, VVMs, and the HIV dipstick. USAID start-up funding has also led to substantial support from other donors, allowing USAID funds to be reassigned to other projects (e.g., vaccine stabilization, contraceptive barriers, jet injectors, malaria diagnostics).

INVOLVEMENT OF AND COMMITMENT TO PARTNERS

HealthTech projects are dependent on collaborations and partnerships with public, private, and commercial institutions. Development of these relationships requires not only business savvy, know-how, and negotiating skills but also a basis of trust, evident reliability, track record, and staying power. While the funding cycles of USAID and other donors are generally limited in time and variable in scope, the partners have been able to depend on the overall reliability and durability of the HealthTech portfolio, sustained by the combination of USAID-lead funding, co-investors, and in-kind contributors.

RISK MANAGEMENT

In addition to the technical risks inherent in innovation, working with the private sector on partnerships for developing-country markets also involves risks that require careful management. The selection of the companies to work with invariably involves trade-offs—large corporations offer the advantages of size, capital, and global distribution systems, but they usually have their own agendas and priorities and often consider these projects as small and unprofitable and therefore treat them as sidelines. Years can go by before commitments are made (e.g., Pfizer's involvement in injectable contraceptives in the Uniject device) or companies may withdraw or change their position on their participation for various reasons (e.g., Boehringer Ingelheim's involvement in single-dose packaging of nevirapine).

Small companies, on the other hand, may be eager to partner with HealthTech but present other challenges: financial solvency, lack of knowledge and equipment for production, or lack of experience with public-sector or developing-world markets. For small- to medium-sized firms in developing countries, challenges include variable or conflicting regulatory systems; prevailing standards of GMP and quality management, and aggressive (sometimes destructive) competition from deep-pocket multinational firms. HealthTech has had to create a range of remedial interventions including identifying sources of loan financing or investing partnerships, market definition, introducing firms to public stakeholders, promoting the role of local manufacturers, and spending more time and effort in training, setting up systems, and quality monitoring.

Durability and reliability of sources of supply of essential components of products (such as recombinant antigens or monoclonal antibodies for diagnostic tests for immunodiagnostics tests) have been a major source of risk. These unique components are often created by individuals in universities or small companies. Unless they find their way into prime industrial-world products, they often sit on refrigerator shelves with little commitment to long-term maintenance on the part of proprietors. Back-up sources must be found or alternative reagents validated, then continuing sources of supplies guaranteed in order to manage this risk.

INFLUENCING POLICIES

A key aspect of HealthTech's work is in understanding the policy environments into which technologies will be introduced, especially ones that will impact current practices. HealthTech has to play a substantial advocacy role in order to be influential and instrumental in changing the policies and best practice guidelines of the international health agencies and ministries of health. This can often take years. Meanwhile, HealthTech must retain technical depth, global vision, diplomatic skills, and a well-established record of constructive involvement. HealthTech has earned this basis of trust and continues to be invited to participate in WHO and UNICEF deliberations, frequently as the only NGO at the table. Similarly, to be prepared to respond to the needs of donors and agencies for technical problem solving, strategy development, or needs assessment, HealthTech must maintain a critical mass of experienced technical experts and resources.

The HealthTech portfolio management approach has resulted in a deep knowledge and experience—resources that can consistently and at short notice provide these high-value contributions. However, this capacity cannot be maintained on the basis of short-term technical assistance projects alone. To maintain their skills and build their experience, staff must be deeply involved in developing technologies that address the health care needs of developing-world populations. Also, to maintain this valuable workforce, HealthTech must continue to tackle new challenges addressing priority needs of the target populations. A balanced combination of portfolio product development and on-call technical and advisory assistance is sustainable and achieves multiple goals.

THE EXPANDING ROLE OF HEALTHTECH

The original concept of HealthTech in 1987 was to develop products to the point of hand-off to the private sector and to play a diminishing role thereafter. By the middle of HealthTech II (1992), it had become evident that a facilitating, bridging partner still needs to be involved well beyond the transfer itself. Commercial partners were critical to achieving sustainable supply but were often inexperienced or unwilling to cope with the complex and multilayered policy, regulatory, and financial environments associated with developing-world public-sector health programs. It subsequently became evident that the international and developing-country health care communities were themselves largely ineffective at introducing and absorbing innovation. New techniques and strategies were required to move disruptive new products into national health care programs.

Additional creative approaches were required for technologies like VVMs and the Uniject device. These are component products that have to be sold to another layer of industry (e.g., the vaccine manufacturers) and incorporated into other products before health care programs can use them.

Multidisciplined HealthTech product teams were formed with business as well as technical and health/field expertise participating fully in project planning right from start-up. The policy environment, commercial landscape, and developing-country settings for acceptance of the new technologies were analyzed early in the process. Adjusting global policy, best practice guidelines, and service delivery budget allocations to take advantage of the new technologies often requires many years of policy dialog, international debate, and evidence gathering from diverse field settings.

ADVANCING NEW CLASSES OF PRODUCTS

HealthTech is now involved in all phases of the value chain for new technologies. The core objective is to address developing-world health care problems. De novo product development is just one approach and is only considered if no suitable existing or adaptable technologies can be identified. HealthTech also seeks to stimulate competition, influence policy, and model operational use to advance a complete class of products (e.g., AD syringes, needle removers for management of sharps, point-of-care rapid diagnostics, freeze-proof vaccine refrigerators). Learning the lesson from the length of time required for official recognition of the widespread reuse of contaminated syringes and needles, HealthTech has also been proactive in building the evidence base to support global policy change and introduction of remedial technologies (e.g., preventing damage to vaccines from freezing). Although HealthTech has no specific mandate for capacity building, it has had a major influence in the development of the Indian health products industry to develop and supply point-of-care rapid diagnostics, facilitated local capacity to produce safe injection technologies, and improved GMP and continuous quality improvement in medical device industries.

STRATEGIES TO MINIMIZE THE DISRUPTIVE EFFECTS OF NEW TECHNOLOGIES

International and local authorities concerned with developing-world health care programs have a limited capacity for absorption of innovation and change. Changes in standard operating procedures can incur an enormous burden of cost and effort for retraining, logistics, and adjustments in budgets and policy. For this reason, HealthTech has aimed to minimize disruption while at the same time introduce innovations that can ultimately reduce dangerous practices, reach more people in need, improve program effectiveness and efficiency, or address a wider array of health problems.

Strategies to minimize disruption include designing an incremental approach to change. An example of this is injection safety, a widespread multidimensional problem involving syringe re-use, accidental injuries from needles and sharps, disposal of infectious waste, aspiration, and unnecessary injections. Analysis early in the HealthTech program suggested that syringe reuse presented the greatest risk. A sequence of solutions was envisaged which could be gradually introduced, but initial effort went into developing the AD syringe. The syringe was designed to take the place of standard disposable syringes and needles and required little or no retraining. However, it enforced behavior change by locking up after a single fill/inject cycle, thereby preventing reuse. Initial designs were focused upon immunization because doses of vaccines were fixed and immunization programs were highly supported and coordinated internationally through the WHO-sponsored EPI. It was felt that the immunization community would understand and support the introduction of these products. In fact, WHO, UNICEF, and UNFPA issued a policy statement: “The joint statement on the use of auto-disable syringes in immunization services” in 2003, which stated that “the auto-disable syringe is the equipment of choice for administering vaccines, both in routine immunization and mass campaigns.”

At the same time, it was understood that unsafe injections for curative interventions were far more numerous and would eventually have to be dealt with, but would take much more time and development of awareness. For this purpose, HealthTech helped to found SIGN with the

secretariat in WHO. In addition, alternative designs of safety syringes were reviewed and assistance given to selected developers with designs that offered the additional flexibility of use required for curative applications as well as the potential for technology transfer to developing-world syringe manufacturers.

HealthTech then started applying these same technologies and principles of safe injection to other uses of needles and syringes such as injectable contraceptives, antibiotics for treatment of infection in newborns, and treatments for postpartum hemorrhage. Each time, HealthTech staff have been able to draw on past experiences, now applied to a new set of players and industry partners.

Once the SoloShot syringe, the HealthTech-developed AD syringe system for immunization, was transferred to a producer and appeared to be accepted by the key gatekeeper organizations, HealthTech addressed the next solutions in the sequence—needle-stick injury and infectious sharps waste management. A new approach was envisaged involving the safe removal and encapsulation of needles at the point of use, a process dubbed "defanging." Several technologies were designed and others identified through a landscape analysis. HealthTech assisted selected developers to adapt their product to meet a set of criteria, which included low-cost, manual activation and the ability to also destroy syringes. Close interactions with WHO and significant modeling of use in the field were necessary to gain status for needle removers as an acceptable practice. These technologies were relatively nondisruptive because they were easily accepted and taken up by health care providers motivated by concerns over the large number of used single-use AD syringes and the absence of waste management infrastructure. (For more information, please see the case study on safe injection technologies that will be available to the reviewers during the site visit to PATH in Seattle.)

Attention is now being given and support sought for introducing technologies to prevent accidental needlestick. Parallel development has also focused on eliminating needles through design and adaptation of a new generation of jet injectors.

This process of incremental problem solving with minimal disruption continues and has been applied to several other problem areas including: thermal instability of vaccines (VVMs, freeze-prevention technologies, hybrid power refrigerators, sugar-glass stabilization of vaccines) and vaccine wastage and access (VVMs, Uniject device, dose-sparing intradermal jet injectors).

SUMMARY OF PROGRAM LIMITATIONS AND STRENGTHS

CHALLENGES AND IMPEDIMENTS TO HEALTHTECH SUCCESSES

Following is a summary of some of the program-wide challenges that the HealthTech program has faced over the years. Many of these have been mentioned already in the context of the topics described above. There also have been many challenges that are unique to each specific technology project; several of those are summarized in the sample product histories (case studies).

- Despite being quite successful at leveraging funds through cofunders and partners, HealthTech has usually not had enough up-front committed funds to conduct product development as a commercial business would. The incremental, annual funding approach of the US Government and other donors has resulted in longer timelines and chronic

uncertainty in planning beyond the current funding cycle. The longer development times resulting from limited funds has sometimes resulted in donor fatigue (e.g., gonorrhea test).

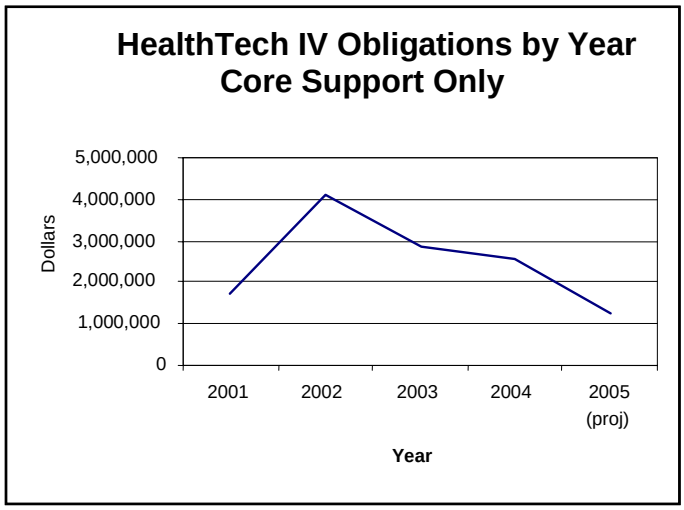
- In order to keep donors interested and willing to support the work, HealthTech frequently has to demonstrate and promote concepts of products a long time before they are actual available products. This has sometimes raised expectations among potential users about availability of technologies. Subsequently, early adopters have been frustrated by the long delivery times for the products.
- USAID funding allows only limited HealthTech involvement in the introduction phase. Funds have been used up in the development phase. Again, due to the limited absorption capacity and general resistance to change, the introduction phase can take years of time and investment. PATH has found ways to keep the projects going but has had to rely on cofunding and the commercial sector to do so, at the expense of time.
- Similarly, there has not been enough funding to satisfactorily follow up with technology transfer recipients for validation of the manufactured technology, quality control or for providing assistance with marketing. HealthTech may lose track of what has happened with products, once they go off the USAID list.
- USAID does not often take the opportunity to gain public credit for successful technologies that it has supported and that are now used globally with high impact (e.g., SoloShot syringes, VVMs, Uniject devices for vaccines).
- Over the 18 years of HealthTech, turnover of project officers/CTOs at USAID has meant that the agency's institutional memory about HealthTech—its process, approaches, and successes—is frequently lost. Fortunately, the same two project officers with a high commitment to, and understanding of, the project have been on board for the past eight years, but as of May 1, 2005, we will be starting with a new person again.
- With some exceptions (India, Indonesia), the involvement of USAID Missions over the years has been minimal. Either they do not understand how technologies fit into their local plans or they do not have the time. As a result, HealthTech is missing USAID advocates in developing countries. Frequently HealthTech staff work directly with other NGOs and ministries of health, without the benefit of USAID involvement on the ground.
- Staff at USAID/W are often unaware of the many and active collaborations of HealthTech with others NGOs, agencies, and governments, especially WHO. USAID has rarely capitalized on their successful pioneering investments in new technologies to enhance the agency's image with the public or congress.

CHANGES IN STRUCTURE AND STRATEGIES AT USAID AND IMPACT ON THE PROGRAM

Support for the portfolio approach extended into HealthTech II, although tolerance for long product development timelines began to wane during the major USAID reorganization and funding crises of 1994–1995. The project was ultimately extended into a third five-year term as it became evident that several technologies advanced under the project were being endorsed and taken up by international agencies. However, the new emphasis on strategic objectives (SO) at USAID diverted resources and management perspectives away from global, "pan-SO" projects that

benefited several different areas of primary health care. The flexibility of the program and tolerance for long development timelines were markedly reduced. SO managers are accountable for their specific sectors and must decide individually the size of budgets to be allocated to the HealthTech program. The current incentives for SO managers are to focus on shorter-term gains and to avoid initiating investment in developments that go beyond current funding cycles. The consequence is a trend towards smaller, more discrete, consultancy-type projects, rather than research and development projects with a longer-term horizon, and a smaller aggregate budget for the overall program. This trend has been especially impactful during the last three years. Funding allocated by USAID for the final year of HealthTech IV is approximately the same budget obligated to HealthTech I in 1987 ($1,000,000), as shown in the following graph (see Figure 2).

Figure. 2



Paradoxically, the portfolio approach relies on advancing a pipeline of technologies with maximum flexibility over budget allocations, a careful balance of activities across the value chain (the different stages of development and diffusion) in order to maintain the full set of required capabilities. It also requires a longer-term commitment to coinvestors, collaborators, and commercial partners similar to the typical ten-year timelines for medical product development in the private sector. The consequence of current trends in USAID SO-focused budgeting in the absence of a cross-cutting perspective is to erode the ability of HealthTech to maintain a dynamic portfolio. At stake is the ability to maintain the broad range and depth of capability necessary for a creative technology resource and the resulting reduction in opportunities to attract cofunding and development partners. The program can provide high-quality technical consultancies and problem solving as a collateral benefit of the build up of technical and management talent. However, this capability cannot be sustained indefinitely in the absence of core support for a dynamic product development portfolio. The program requires a rich and constant inflow of new opportunities and ongoing processes to graduate or terminate existing products.

WHAT IS HAPPENING WITH OTHER DONORS?

USAID's pioneering investment in development of a portfolio of technologies under HealthTech remains unique among donor agencies. New funding modalities have emerged in recent years for advancing key vaccines and drugs with investments in the tens of millions of dollars. However, these approaches are often based on upstream research, singularly focused, and managed through large public and private partnerships and alliances. Or they focus on large vertical efforts around prevention or treatment that are preidentified. The advancement of technologies for improvement of drug and vaccine delivery, disease detection, program efficiency, access by poor population, and the translation of innovative products to mainstream use remains a severely under-funded area.

THE IMPACT OF GLOBALIZATION

At the same time that support for the portfolio approach to technology solutions for resource-poor populations has eroded, the opportunities for effective partnerships and catalysts of the commercial sector have increased. The trend toward globalization has stimulated commercial interest in developing-world markets. As a consequence, requests to HealthTech from the private sector for collaboration in advancing or adapting health care products have increased significantly in the past few years. While for-profit firms remain concerned and inhibited by the complexities and limited returns of developing-world public health markets, the opportunity for risk-sharing, leveraging of costs, and providing incentives to commercial partners for important new technologies is higher than ever.

Similarly, large academic, not-for-profit and parastatal R&D institutions are seeing the need to expand their focus and to apply their core capacities to address the large disparities in health research between developed- and developing-world health priorities. PATH/HealthTech has received at least six requests from such institutions in the past year and is currently undertaking or planning collaborations with Massachusetts Institute of Technology and the Boston University conglomerate (Center for Integration of Medicine and Innovative Technology–CIMIT), Battelle NorthWest, Seattle Biomedical Research Institute, the Foundation for New Innovative Diagnostics, and several divisions of the WHO. These alliances are predicated on the assumption that donors can still be convinced to support the longer horizons of product development. These inquiries represent major opportunities to leverage even a modest investment by USAID as the lead investor, but the investment has to be large and flexible enough to support the core capabilities and expertise required to respond to these leads.

STRENGTHS OF HEALTHTECH

- HealthTech has deep knowledge and experience and an excellent reputation for working with the private commercial sector as a bridging organization that advocates for the public-sector needs and constraints, but recognizes the needs of the private sector as well. PATH has developed specific approaches and guidelines for public-/private-sector partnerships focused on developing-world needs for technologies. These are based on goals of guaranteeing affordability and availability of technologies, while creatively allowing the private sector to make profits.
- HealthTech has achieved a remarkably efficient use of a low level of resources compared to similar projects in the private-sector. In some cases, the ratio of the private sector investment has been 10 to 1, as with BD's investment in the Uniject device. (See Table 3.) HealthTech has achieved this by successfully leveraging USAID investments with private-sector investments as well as funds from other donors.
- HealthTech uses a multidisciplinary approach. HealthTech teams consist of technical staff, public health staff, and business development staff. Many HealthTech staff who are adept at troubleshooting difficult problems have been long-term employees of PATH and have accumulated deep knowledge and experience in addressing the complex problems inherent in the Healthtech mission.

- HealthTech's methodologies for working on products designed specifically for low-resource settings are well developed. Staff understand the context and realities of the field, how to define performance specifications accordingly, and then how to develop and test products to those specifications. End users are involved from the beginning in the design of technologies. Staff also brings broad knowledge of developing-country markets, public health systems, regulatory processes, and intellectual property management.
- HealthTech staff have a deep understanding of international health policy and infrastructure, and significant involvement in global discussions and recommendations regarding the use of technologies in low-resource settings. Participation on WHO committees and other international entities on technology-related topics are frequent. Staff understand how to work within the system to influence the environment into which technologies are introduced, i.e., through policy changes or changes in practices that have to occur.

USAID'S FUTURE INVESTMENTS IN HEALTH TECHNOLOGIES

One of the major purposes of this review of the HealthTech program is to critically evaluate the impact of USAID's investments in health technologies and to reconsider USAID's continuing support for this activity. As demonstrated in this briefing document, we believe that USAID has made many wise and successful investments that are already positively impacting health globally. Furthermore, many of these investments are sustainable and will continue to pay off for many years as the products and technologies incubated under the HealthTech program reach more and more markets and end users. They will be available, whether or not USAID continues to be involved, because HealthTech has successfully passed the responsibility to other donors for further development and/or the products have been taken up by the private sector. On the other hand, HealthTech's continued role as a partner with the private-sector companies through the phase of early introduction and diffusion will increase the likelihood of their effectiveness.

However, at this time of reassessment, we should not look only at USAID's past history of leadership and foresight in this area, but also to their future role and the difference they can make with the next generation of health technologies. At a time when technological advances are becoming more and more suitable for adaptation for low-resource settings, USAID can seize the opportunity to capitalize on the expertise and experience already in place. At a time when there is an outside call for more support of science and technology focused on developing countries, USAID can step up and take the lead because the resources are already available.

Strong rationale for a major and lead donor like USAID to invest in health technologies is accumulating. The interim report to the USAID administrator on "Science and Technology in US Foreign Assistance" focuses on this issue.[4] Some of the preliminary recommendations get right to the heart of the type of work that HealthTech carries out on USAID's behalf. In defining the

[4] Committee on Science and Technology in Foreign Assistance. Development, Security, and Cooperation Policy and Globla Affiars. *Science and Technology in US Foreign Assistance. Interim Report to the Administrator, US Agency for International Development.* 2004.

science and technology that is supported by US foreign assistance, the committee notes that science and technology:

> *". . . Encompasses the capacity of the public and private sectors in developing countries to:*
>
> *–Carry out research, development, technology transfer, technology adaptation and technology application activities.*
>
> *–Assess the technical and economic merits of technologies being considered for use in the country"*

The report goes on:

> *"To support these activities, USAID should have S and T capabilities to (among other things):*
>
> *–Evaluate available technologies and encourage development of emerging technologies that are relevant to USAID's interests;*
>
> *–Incorporate technologies, research findings and modern management methods in USAID projects facilitating the transfer of these methods and technologies to developing countries."*

In the recent series on the Millennium Project in the March issue of Lancet, the writers of the article on "Reinventing global health: the role of science, technology, and innovation"[5] say:

> *"The first step in improving the application of science, technology and innovation in development is to align government structures with research initiatives. This cannot be done without placing technological innovation at the centre of the development process."*
>
> *"International organizations such as WHO and the international financial institutions should expand the application of science and technology, promote technological innovation in developing countries, and adjust rule-making and standard setting activities to better meet the interests of developing countries . . .*
>
> *"Nothing short of a clear commitment to the role of technology in development will help developing countries benefit from the growing global body of scientific and technical knowledge."*

From these perspectives, HealthTech is a central player in USAID's capacity to fulfill these development mandates. Healthtech also represents a means by which US industry can be induced to apply their innovative capacity, products and services to the needs of underserved populations. The result of these facilitated collaborations with industry on behalf of US overseas development goals has and will continue to be the application of US ingenuity and business efficiency toward USAID strategic objectives as well as the realization of new and expanded markets for US health product industries.

PATH remains fully committed to the mandate and principles of the HealthTech program, and looks forward to continuing this successful collaboration with USAID in the future. Together we can continue to foster and diffuse health innovations on behalf of developing country populations, by applying and adapting this unique resource built with USAID support over the past two decades.

[5] Juma C, Yee-Cheong L. Reinventing global health: The role of science, technology, and innovation. *The Lancet*. .2005;365:1105-110.

APPENDICES

1. PATH's Guiding Principles for Private Sector Collaboration
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12. USAID and Cofunding Support for HealthTech Products 1987-2004

SUPPLEMENTAL MATERIAL UNDER SEPARATE COVER

Technology Solutions for Global Health

mfrp24026